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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,611	01/31/2006	Gerhard Liepold	13503PCTUS	7406

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EXAMINER	
TIETJEN, MARINA ANNETTE	

ART UNIT	PAPER NUMBER
3753	

MAIL DATE	DELIVERY MODE
12/19/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,611	LIEPOLD ET AL.	
	Examiner	Art Unit	
	MARINA TIETJEN	3753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09/17/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-90* is/are pending in the application.

4a) Of the above claim(s) *68-90* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Election

1. Claims 50-90 are presently pending in this application. Claims 1-29 have been canceled.

2. Applicant's election with traverse of Group I in the reply filed on 09/17/2008 is acknowledged. The examiner accepts the proposed Groups presented by the applicant.

3. Claims 68-90 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group, there being no allowable generic or linking claim. .

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 55, line 5 recites the limitation "a substantially uniform cross-section", and lines 6-7 recite "the uniform bore portion". It is unclear what is meant by a "uniform" cross-section and "uniform" bore. Uniform in what manner?

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 50-58 and 62-63 are rejected under 35 U.S.C. 102(b) as being anticipated by Newberg (6491283).

Regarding Claim 50, Newberg discloses a valve (Fig. 9) comprising a body 10, 100 (Fig. 9) having first 103 (Fig. 9) and second open 32 (Fig. 9) ends and a passageway 11 (Fig. 9) for fluid between the ends, the first end 103 including a first coupling means 105 (Fig. 1, col. 6, lines 30-36) for sealingly connecting the body 10, 100 about an opening (not shown, col. 6, lines 30-36) of a first external device (not shown) and a seal 21, 84 (Fig. 9) blocking an open area 20 (Fig. 1) of the first end 103, the valve further including a seal displacement means (74, 130, and piston in combination, see labeled Fig. 9 below) movable within the body so as to interrupt the seal 21, 84 permitting fluid to pass along the passageway 11 between the ends 103, 32, the coupling means 105 and the seal presenting a sterilisable mating surface for sealingly mating with a mating surface about the opening in the first external device (col. 6, lines 30-36), wherein the seal 21, 84 is formed between a first plastics portion 84 movable by the seal displacement means 74, 130 and a second plastics portion 21 disposed about the open area of the first end 103 of the valve,

wherein the second plastic portion 21 has a protruding sharp rim (Fig. 9) and the first plastic portion 84 of the seal has a curved surface area (Fig. 9) so that when the valve is in the closed position, the sharp rim (of 21) engages the curved surface area and displaces a portion of the curved surface area thereby elastically deforming the materials of the sharp rim and the curved surface area to seal the opening of the valve.

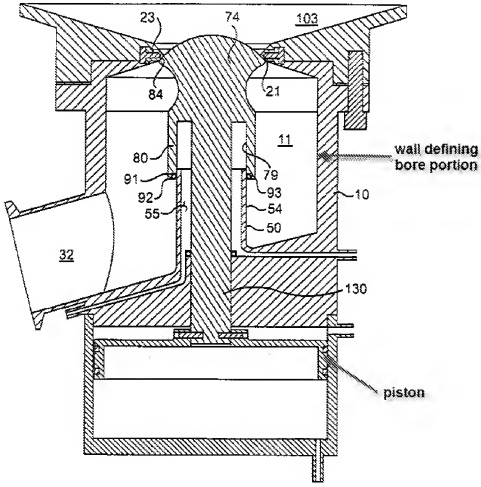

FIG. 9

Regarding Claim 51, Newberg discloses the engagement of the sharp rim 21 with the curved surface area occurs during a linear motion of the sharp rim 21 relative to the curved surface area.

Regarding Claim 52, Newberg discloses the first plastic portion 84 is integrally formed (Fig. 9) with the seal displacement means 74, 130.

Regarding Claim 53, Newberg discloses the first plastic portion 84 is provided by a plastic plug 74 integrally formed (Fig. 9) with the seal displacement means 74,130.

Regarding Claim 54, Newberg discloses the second plastic portion is integrally formed with the body of the valve (col. 15, lines 5-7).

Regarding Claim 55, as best understood, Newberg discloses the second plastic portion 21 comprises a wall defining a bore portion (see labeled Fig. 9 above) having a cross-section converging towards the first end 103 of the valve which in turn leads to a wall defining a bore portion (best seen in labeled Fig. 3 below) having a substantially uniform cross-section which is located adjacent the first end 103 of the valve, the boundary between the wall defining the converging bore portion and the wall defining the uniform bore portion defining the sharp rim 21, the first plastic portion 84 having a body portion 74 with a cross-section converging towards the first end 103 of the valve and leading to an end portion with a uniform cross-section, the end portion being adjacent the first end 130 of the valve in use and a transitional surface between the external surface of the body portion 100 and the external surface of the end portion of the first plastic portion 84 defining the curved surface area so that when the opening of the valve is sealed the sharp rim 21 engages the curved surface area and displaces a

portion of the curved surface area thereby elastically deforming the materials of the sharp rim 21 and the curved surface area.

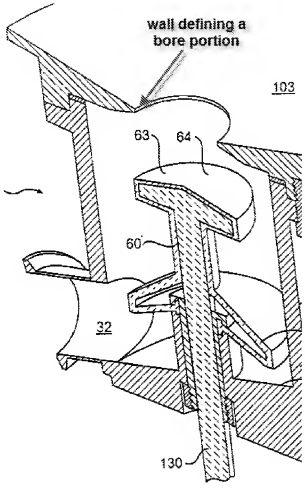

FIG. 3

Regarding Claim 56, Newberg discloses the curved surface area (of plug 74) has a predetermined radius (Fig. 9).

Regarding Claim 57, Newberg discloses the second end 32 of the body 10, 100 comprises a second coupling means 34 (Fig. 1, col. 7, lines 20-22) with a mating

surface for sealingly connecting the body about an opening of a second external device (not shown).

Regarding Claim 58, Newberg discloses the distance between the mating surfaces of the first 105 and the second 34 coupling means remains unchanged during movement of the seal displacement means 74, 130 within the body 10, 100 between open and closed positions of the valve.

Regarding Claim 62, Newberg discloses the body comprises a hollow housing 10 (Fig. 9) extending between the first 130 and the second open ends 32.

Regarding Claim 63, Newberg discloses the seal displacement means comprises a piston (see labeled Fig. 9 above) slidably movable within the housing, the piston having the first plastic portion 74 formed at the top end thereof.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 61 and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Newberg (6491283) in view of Jougla (6237639).

Regarding Claims 61 and 64-65, Newberg discloses the invention as essentially claimed, except for means for displaying to a user the actuation state of the valve, an operating means having an actuator externally mounted on the body and movable between a first and a second end position, the actuator being linked with the seal displacement means so that movement of the actuator between the first and the second end positions causes the seal displacement means to translate along the passageway between open and closed positions, and wherein the actuator is linked with the seal displacement means via a cam pair.

Jougla teaches an operating means 9 having an actuator 10 externally mounted on a body 1 and movable between a first and a second end position, the actuator 10 being linked with a seal displacement means 13 so that movement of the actuator 10 between the first and the second end positions causes the seal displacement means to translate along a passageway between open and closed positions, wherein the actuator 10 is linked with the seal displacement means 13 via a cam, and wherein the actuator 10 position displays to the user the actuation state of the valve (based on the relative position of the actuator 10 to its overall stroke), for the purpose of providing a coupling

and drive means that is simple in structure (col. 2, lines 16-17) yet ensures the reliability of the valve movement (col. 2, lines 51-52).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Newberg's invention to include an operating means having an actuator externally mounted on the body and movable between a first and a second end position, the actuator being linked with the seal displacement means so that movement of the actuator between the first and the second end positions causes the seal displacement means to translate along the passageway between open and closed positions, wherein the actuator is linked with the seal displacement means via a cam pair, and wherein the actuator position displays to the use the actuation state of the valve, as taught by Jougla, for the purpose of providing a coupling and drive means that is simple in structure yet ensures the reliability of the valve movement.

Regarding Claim 66, Newberg discloses the invention as essentially claimed, except for at least one guide element is provided in the valve to prevent rotational motion of the seal displacement means and to permit the seal displacement means to move only linearly in the passageway.

Jougla teaches two guide elements 20 provided in the valve to prevent rotational motion of the seal displacement means 13 and to permit the seal displacement means 13 to move only linearly in the passageway, for the purpose of ensuring reliable valve movement (col. 2, lines 51-56).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Newberg's invention to include at least one guide

element is provided in the valve to prevent rotational motion of the seal displacement means and to permit the seal displacement means to move only linearly in the passageway, as taught by Jougla, for the purpose of ensuring reliable valve movement.

6. Claims 50 and 59-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leipold et al. (WO 03/090842) in view of Trumbower et al. (7370673).

Regarding Claim 50, Leipold et al. disclose a valve 100 (Fig. 1a) comprising a body 2 (Fig. 1a) having first 2L (Fig. 1a) and second 2p (Fig. 1a) open ends and a passageway (Fig. 1a) for fluid between the ends, the first end 2L including a first coupling means (Fig. 2a) for sealingly connecting the body 2 about an opening 4c (Fig. 1a) of a first external device 4 (Fig. 1a) and a seal 2a (Fig. 1a) blocking an open area of the first end 2L which in use is placeable in register with the opening 4c of the external device 4, the valve further including a seal displacement means 1 (Fig. 1a) movable within the body 2 so as to interrupt the seal 2a permitting fluid to pass along the passageway between the ends, the coupling means and the seal 2a presenting a sterilisable mating surface 12 (Fig. 1a) for sealingly mating with a mating surface 13 (Fig. a1) about the opening 4c in the first external device 4, wherein the seal 2a is formed between a first plastics portion 1f (Fig. 1i) movable by the seal displacement means 1 and a second plastics portion disposed 2b about the open area of the first end of the valve100.

However, Leipold et al. fail to disclose one of the plastic portions has a protruding sharp rim and the other plastics portion of the seal has a curved surface area so that

when the valve is in the closed position, the sharp rim engages the curved surface area and displaces a portion of the curved surface area thereby elastically deforming the materials of the sharp rim and the curved surface area to seal the opening of the valve.

Trumbower et al. teach a valve member portion 619 has a protruding sharp rim 689 (Fig. 16a) and another plastics portion of a seal 642 (Fig. 19a) has a curved surface area (best seen in Figs. 18, 18a) so that when the valve is in the closed position, the sharp rim 689 engages the curved surface area 642 and displaces a portion of the curved surface area thereby elastically deforming the materials of the sharp rim and the curved surface area to seal the opening of the valve, for the purpose of eliminating misalignment of the valve member 619 relative to the opening, wherein the curved surface 642 acts as a guide to center the valve member.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Leipold's invention such that one of the plastic portions has a protruding sharp rim and the other plastics portion of the seal has a curved surface area so that when the valve is in the closed position, the sharp rim engages the curved surface area and displaces a portion of the curved surface area thereby elastically deforming the materials of the sharp rim and the curved surface area to seal the opening of the valve, as taught by Trumbower et al., for the purpose of eliminating misalignment of the valve member relative to the opening, wherein the curved surface acts as a guide to center the valve member.

Regarding Claim 59, Leipold et al. disclose the seal displacement means 1 travels at least partially outside of the second end 2p of the body 2 on actuation of the valve 100.

Regarding Claim 60, Leipold et al. disclose the displacement means 1 comprise first 1f (Fig. 1i) and second ends 110 (Fig. 1i), the first end 1f comprising the first plastic portion and the second end 110 comprising a coupling means for sealingly connecting the displacement means 1 about an opening of a second external device (not shown).

Regarding Claim 61, Leipold et al. disclose means 2r (Fig. 1d) for displaying to a user the actuation state of the valve 100.

Regarding Claim 62, Leipold et al. disclose the body 2 comprises a hollow housing 2i (Fig. 1a) extending between the first 2L and the second 2p open ends.

Regarding Claim 63, Leipold et al. disclose the seal displacement means 1 comprises a piston (Fig. 1a) slidably movable within the housing 2, the piston having the first plastic portion 1f formed at one end thereof.

Regarding Claim 64, Leipold et al. disclose an operating means having an actuator 50 (Fig. 10b) externally mounted on the body 2 and movable between a first and a second end position, the actuator 50 being linked with the seal displacement means 1 so that movement of the actuator 50 between the first and the second end positions causes the seal displacement means 1 to translate along the passageway between open and closed positions.

Regarding Claim 65, Leipold et al. disclose the actuator 50 is linked with the seal displacement means 1 via a cam pair 50c (Fig. 10b).

7. Claim 67 is rejected under 35 U.S.C. 103(a) as being unpatentable over Leipold et al. (WO 03/090842) in view of Trumbower et al. (7370673) further in view of Astier (1387446).

Regarding Claim 67, Leipold et al. in view of Trumbower et al. disclose the invention as essentially claimed, except for a seal provided at both the first and the second open ends of the body, each seal having a seal displacement means movably disposed within the passageway of the body so that the first and/or second ends may be sealed or opened.

Astier teaches a seal 9 (Fig. 1) provided at both a first and second open ends 15 (Fig. 1) of a body 1 (Fig. 1), each seal 9 having a seal displacement means 6 (Fig. 1) movably disposed within the passageway (Fig. 1) of the body 1 so that the first and second ends 15 may be sealed or opened for the purpose of ensuring tight closing of the apparatus since any escape of the fluid is successively opposed by the two sealed ends (col. 2, lines 82-85).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Leipold et al.'s invention in view of Trumbower et al. such that a seal is provided at both the first and the second open ends of the body, each seal having a seal displacement means movably disposed within the passageway of the body so that the first and/or second ends may be sealed or opened, as taught by Astier, for the purpose of ensuring tight closing of the apparatus since any escape of the fluid is successively opposed by the two sealed ends.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARINA TIETJEN whose telephone number is (571) 270-5422. The examiner can normally be reached on Mon-Thurs, 9:00AM-5:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GREG HUSON can be reached on (571) 272-4887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John Rivell/
Primary Examiner, Art Unit 3753

/M. T./
Examiner, Art Unit 3753